

TITLE 21 - FOOD AND DRUGS
CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER X - MISCELLANEOUS

§ 393a. Office of Pediatric Therapeutics

(a) Establishment

The Secretary of Health and Human Services shall establish an Office of Pediatric Therapeutics within the Food and Drug Administration.

(b) Duties

The Office of Pediatric Therapeutics shall be responsible for coordination and facilitation of all activities of the Food and Drug Administration that may have any effect on a pediatric population or the practice of pediatrics or may in any other way involve pediatric issues, including increasing pediatric access to medical devices.

(c) Staff

The staff of the Office of Pediatric Therapeutics shall coordinate with employees of the Department of Health and Human Services who exercise responsibilities relating to pediatric therapeutics and shall include—

- (1) one or more additional individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population; and
- (2) one or more additional individuals with expertise in pediatrics as may be necessary to perform the activities described in subsection (b) of this section.

(Pub. L. 107–109, § 6, Jan. 4, 2002, 115 Stat. 1414; Pub. L. 110–85, title III, § 306(a), Sept. 27, 2007, 121 Stat. 864.)

Codification

Section was enacted as part of the Best Pharmaceuticals for Children Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Amendments

2007—Subsec. (b). Pub. L. 110–85 inserted “, including increasing pediatric access to medical devices” before period at end.